

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MARYLAND**

UNITED STATES OF AMERICA,

Plaintiffs,

v.

NADER POURHASSAN, and
KAZEM KAZEMPOUR,

Defendants.

Case No. 8:22-cr-0440-PX

**DEFENDANT NADER POURHASSAN'S
MOTION TO DISMISS THE INDICMENT**

Defendant Nader Pourhassan, through counsel, moves this Court, pursuant to Federal Rule of Criminal Procedure 12(b)(3)(B)(v), to dismiss the Indictment Counts One, Two, Four, Five, Six, Nine, Ten, Eleven, Twelve and Thirteen for failure to state an offense.

The grounds for the motion are set forth in the accompanying memorandum of law.

Dated: July 25, 2023

Respectfully submitted,

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**IN THE UNITED STATES DISTRICT COURT
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UNITED STATES OF AMERICA,

Plaintiff,

v.

NADER POURHASSAN, and
KAZEM KAZEMPOUR,

Defendants.

Case No. 8:22-cr-00440-PX

**DEFENDANT NADER POURHASSAN’S MEMORANDUM OF LAW IN
SUPPORT OF HIS MOTION TO DISMISS
THE INDICTMENT**

I. INTRODUCTION

Defendant Nader Z. Pourhassan (“**Dr. Pourhassan**”), by and through undersigned counsel, moves this Honorable Court to enter an Order dismissing Counts One, Two, Four, Five, Six, Nine, Ten, Eleven, Twelve and Thirteen of the indictment (the “**Indictment**”). Count One charges Dr. Pourhassan with Conspiracy to Commit Securities Fraud and Wire Fraud under 18 U.S.C. § 371. Counts Two, Four and Nine charge Dr. Pourhassan with Securities Fraud under 15 U.S.C. §§ 78j(b) and 78ff and 17 C.F.R. § 240.10b-5. Counts Five, Six and Ten charge Dr. Pourhassan with Wire Fraud under 18 U.S.C. § 1343. Counts Eleven through Thirteen charge Dr. Pourhassan with Insider Trading under 15 U.S.C. §§ 78j(b) and 78ff and 17 C.F.R. § 240.10b-5.

Central to all of the above charges, is the Indictment’s allegation that Dr. Pourhassan engaged in securities and wire fraud and insider trading when he participated in the making of materially false and misleading representations relating to CytoDyn's investigation and attempted development of leronlimab as a potential treatment for HIV and Covid-19, including the timeline

and status of CytoDyn's regulatory submissions to, and review of leronlimab by, the FDA. Indictment ¶¶ 11(a), 11(b), 12; *see also id.*, at 30-35, 38-39.

According to the Indictment, Dr. Pourhassan made these allegedly false statements to help CytoDyn, a late-stage and single drug biopharmaceutical company, raise money to fund its operations. The Indictment seeks to demonstrate Dr. Pourhassan's fraudulent intent with the allegation that Dr. Pourhassan made overly optimistic statements about drug approval expectations (*see, e.g.* Indictment ¶¶ 28 – 35) to combat CytoDyn's "operating losses" and therefore he "worked aggressively to finance CytoDyn's cash needs by selling equity and debt securities" and that he "raised more than \$200 million by selling equity and debt securities." Indictment ¶ 4.

However, given the critical role biopharmaceutical companies play in combatting deadly diseases and their need to raise capital, the Fourth Circuit has expressly warned courts against permitting accusations of securities fraud to proceed against biopharmaceutical companies and their executives:

Biopharmaceutical clinical trial drug companies constantly find themselves in the hot seat. Not only does their longevity depend on the creation of ground-breaking, experimental drugs designed to combat the world's deadliest illnesses, i.e. Cancer, but also a significant portion of their success turns on the amount of capital raised to explore these uncharted waters, making investors an integral part of the equation. Therefore, we cannot admonish these companies for issuing positive and accurate opinions while "weighing . . . competing facts," and must remind investors to "not expect that every fact known to an issuer supports its opinion statement." It would be a great disservice to stifle biopharmaceutical companies' pursuit of medical advancements by failing to safeguard against an inundation of lawsuits alleging securities-law violations.

Emps. ' Ret. Sys. of Baton Rouge & Par. of E. Baton Rouge v. MacroGenics, Inc., 61 F.4th 369, 388 (4th Cir. 2023) (internal citations omitted).

Consistent with this warning, in *Cozzarelli v. Inspire Pharmaceuticals Inc.*, the Fourth Circuit rejected the use of the federal securities laws for the Indictment's very theory of fraud.

There, the Fourth Circuit affirmed the dismissal of a civil securities class action complaint against a biopharmaceutical company and its CEO, finding in relevant part that:

It is improbable that Inspire would stake its existence on a drug and a clinical trial that the company thought was doomed to failure. Plaintiffs' inference of fraud based on the supposed impossibility of corneal clearing is thus not even plausible, much less convincing.

Plaintiffs' conclusory allegations regarding defendants' motives to defraud also lack merit. Plaintiffs claim that Inspire was motivated to make public statements about diquafosol that were overly optimistic because the company needed to raise money to fund its operations. They also claim that Shaffer had an incentive to puff up the outlook of Study 109 falsely because her compensation was tied to the company's performance. But a strong inference of fraud does not arise merely from seeking capital to support a risky venture. Indeed, the motivations to raise capital or increase one's own compensation are common to every company and thus add little to an inference of fraud. All investments carry risk, particularly in a field like biopharmaceuticals. If we inferred scienter from every bullish statement by a pharmaceutical company that was trying to raise funds, we would choke off the lifeblood of innovation in medicine by fueling frivolous litigation

Cozzarelli v. Inspire Pharms. Inc., 549 F.3d 618, 627 (4th Cir. 2008) (internal citations omitted).

Other courts have reached results consistent with the Fourth Circuit's rejection in *Cozzarelli* of the Indictment's theory of liability. For example, in *Nguyen v. Endologix, Inc.*, the Ninth Circuit Court of Appeals found that the Indictment's theory of fraud not only lacked merit, but did not even satisfy the very low "plausibility" standard applicable in civil cases as set forth in *Bell Atlantic Corp. v. Twombly*, 550 U.S. 544, 556–57 (2007):

Allegations that are implausible do not create a strong inference of scienter. Under the facts alleged, plaintiff's core theory—that the company invested in a U.S. clinical trial and made promising statements about FDA approval, yet knew from its experience in Europe that the FDA would eventually reject the product—has no basis in logic or common experience. Based on plaintiff's complaint, the more plausible inference is that the company made optimistic statements about its prospects for FDA approval because its U.S. testing looked promising, not because the company was quixotically seeking FDA approval for a medical device application it knew was destined for defeat.

Nguyen v. Endologix, Inc., 962 F.3d 405, 408 (9th Cir. 2020); *see also id.*, at 415; *see also City of Edinburgh Council v. Pfizer, Inc.*, 754 F.3d 159, 170 (3d Cir. 2014) (affirming dismissal of securities fraud complaint because, *inter alia*, "the initiation of Phase 3 cost millions of dollars and

required FDA approval, rendering it improbable that defendants would have continued if they did not believe their interpretation of the interim results or if they thought the drug a complete failure”).

For these reasons and as further discussed below, the Indictment’s allegations against Dr. Pourhassan do not even amount to a violation of the *civil* securities or fraud laws. And critically, the U.S. Supreme Court has made clear that courts “must interpret [a] statute consistently, whether we encounter its application in a criminal or noncriminal context.” *Leocal v. Ashcroft*, 543 U.S. 1, 11 n.8 (2004).

Accordingly, the “crimes” with which the Government has charged Dr. Pourhassan simply do not exist. Moreover, even if such crimes theoretically could exist – despite clear Fourth Circuit precedent to the contrary – Dr. Pourhassan lacked notice during the relevant time that the conduct with which he has been charged constituted a violation of the law. Consequently, the charges against him violate the Rule of Lenity and the Due Process Clause of the Fifth and Sixth Amendments to the U.S. Constitution.

As for the remaining counts against Dr. Pourhassan, (Counts Five, Six, Ten and Eleven through Thirteen), they are entirely dependent for their viability on the existence of the securities fraud charges; once those counts are dismissed, those charges must fall.

II. ARGUMENT

As discussed above, the Indictment charges a theory of fraud against Dr. Pourhassan that the Fourth Circuit says does not even amount to a civil violation of the law, and there is no precedent for charging such conduct criminally. Seeking to hold Dr. Pourhassan criminally liable under such circumstances would undermine fundamental principles of lenity and due process.

A. The Rule of Lenity Requires Dismissal of the Indictment.

It is fundamental that “ambiguity concerning the ambit of criminal statutes should be resolved in favor of lenity.” *Liparota v. United States*, 471 U.S. 419, 427 (1985) (quoting *Rewis v. United States*, 401 U.S. 808, 812 (1971)) (internal quotation marks omitted). Indeed, there are “serious consequences flowing from a criminal conviction,” which necessitate strict construction of criminal laws so that “no [person] shall be held criminally responsible for conduct which he could not reasonably understand to be proscribed.” *United States v. Hilton*, 701 F.3d 959, 966 (4th Cir. 2012) (citing *United States v. Lanier*, 520 U.S. 259, 265–66 (1997)).

Importantly, there cannot be one construction for the civil courts and another for the Department of Justice. *See FCC v. Am. Broad. Co.*, 347 U.S. 284, 296 (1954) (Supreme Court held in deciding whether “give-away” programs were illegal, “the broad construction urged by the Commission . . . lack[s] support in the decided cases, judicial and administrative, but also it would do violence to the well-established principle that penal statutes are to be construed strictly”). Thus, where statutes – such as the federal securities laws – have both civil and criminal applications, courts “must interpret the statute consistently, whether [they] encounter its application in a criminal or noncriminal context.” *Leocal*, 543 U.S. at 11 n.8.

Because the Fourth Circuit and other courts have rejected the Indictment’s theory of fraud, there is no basis to criminalize such conduct, and the rule of lenity requires the Indictment to be dismissed against Dr. Pourhassan. *See United States v. R.L.C.*, 503 U.S. 291, 305 (1992) (“the venerable rule of lenity” is “rooted in ‘the instinctive distaste against men languishing in prison unless the lawmaker has clearly said they should’” (quoting *United States v. Bass*, 404 U.S. 336, 348 (1971))).

B. Holding Dr. Pourhassan Liable for Criminal Fraud Would Offend Fundamental Due Process

It is well settled that “[d]ue process bars courts from applying a novel construction of a criminal statute to conduct that neither the statute nor any prior judicial decision has fairly disclosed to be within its scope.” *Lanier*, 520 U.S. at 266. *See also Marks v. United States*, 430 U.S. 188, 191-92 (1977); *Rabe v. Washington*, 405 U.S. 313, 315-16 (1972); *Bouie v. City of Columbia*, 378 U.S. 347, 353-54 (1964). This due process principle stems from the fundamental notion that the state may not impose penalties without clear warning as to what is unlawful conduct and its consequences. Thus, “[w]hen a person of ordinary intelligence has not received fair notice that his contemplated conduct is forbidden, prosecution for such conduct deprives him of due process.” *United States v. Matthews*, 787 F.2d 38, 49 (2d Cir. 1986) (citing *United States v. Harriss*, 347 U.S. 612, 617 (1954), *Lanzetta v. New Jersey*, 306 U.S. 451, 453 (1939)).

Here, the Indictment against Dr. Pourhassan is based on a theory of wrongdoing that the Fourth Circuit has rejected, and other courts have similarly declined to permit. The U.S. Supreme Court has made clear that under the Constitution, lower courts must not permit such a prosecution to proceed. “The fundamental principle that the required criminal law must have existed when the conduct in issue occurred . . . must apply to bar retroactive criminal prohibitions emanating from courts as well as from legislatures.” *Bouie*, 378 U.S. at 354 (internal citations and quotation marks omitted). Thus, “[i]f a judicial construction of a criminal statute is ‘unexpected and indefensible by reference to the law which had been expressed prior to the conduct in issue,’ it must not be given retroactive effect.” *Id.*

In *United States v. Brennan*, the Second Circuit indicated it would reverse the fraud-related convictions of a corporate CEO on these grounds. There, the Government charged the CEO defendant with acting contrary to an alleged fiduciary duty to insurers and making fraudulent and

false statements to such insurers contrary to those duties. On appeal, the Second Circuit found that the prosecution violated the rule of lenity and the requirement of fair notice implicit in the concept of due process. It did so because, in similar civil cases, courts had rejected a similar theory of liability, and there was “no precedent for criminal liability.” *United States v. Brennan*, 183 F.3d 139, 150 (2d Cir. 1999). The Court further stated that “[e]ven if these civil cases would be distinguishable from the facts presented [there], they substantially undercut the notion that defendants had fair notice that nondisclosures regarding reinsurance arrangements and the facts surrounding the Flight 1771 litigation could constitute a crime under the federal mail fraud statute.” *Id.*; *see also Matthews*, 787 F.2d at 49 (rejecting the government’s theory of prosecution where there was a “lack of any precedent for the government’s theory of liability”).

Under the circumstances discussed above, Dr. Pourhassan could not have received fair notice that he would be held criminally liable for his conduct, and the Court should dismiss the Indictment.

C. The Indictment Does Not Otherwise Demonstrate That Dr. Pourhassan Had Notice That His Conduct Was Criminal

As an initial matter, even if the Government seeks to use allegations in the Indictment to distinguish the Fourth Circuit’s decisions in *Cozzarelli* and other cases above – all of which render the Government’s central theory non-actionable – these cases “substantially undercut the notion that [Dr. Pourhassan] had fair notice” that his alleged conduct “could constitute a crime.” *Brennan*, 183 F.3d at 150.

Moreover, the Indictment’s allegations do not otherwise demonstrate that Dr. Pourhassan had notice that his conduct was criminal. By way of example only:

1. Dr. Pourhassan’s alleged stock sales (Indictment ¶¶ 43-44).

The Indictment’s allegations regarding Dr. Pourhassan’s alleged sale of securities did not put him on notice of criminal conduct. Indictment at 26-27, 38-39; *see also* ¶¶ 43-44. Indeed, in *Cozzarelli*, the Court also found that a CEO’s sale of company securities “do not add support to an inference of scienter.” 549 F.3d at 627-28. Here, as in *Cozzarelli*, “[w]hen we consider [Dr. Pourhassan’s] total number of shares and vested stock options as stated in SEC filings,” Dr. Pourhassan continued to retain a substantial ownership interest in CytoDyn.¹ Thus, Dr. Pourhassan’s “total holdings” do not suggest that he “sought to dump [his] shares at an inflated price.” *Id.* at 628. Finally, the Indictment makes no allegation that Dr. Pourhassan sold CytoDyn securities entirely for his own personal benefit, a key missing allegation.²

¹ Dr. Pourhassan invites this Court to take judicial notice of certain relevant public records: EXHIBIT A, SEC Form 4, “Statement of Changes in Beneficial Ownership, Nader Pourhassan.” Dr. Pourhassan sold his options in April and May 2020, and a substantial portion of the sales proceeds enabled CytoDyn to make payments it was owing to Samsung Biologic; and EXHIBIT B, SCHEDULE 14A: Proxy Statement Pursuant to Section 14(a) of the Securities Exchange Act of 1934, at 8, showing that as of May 28, 2020, Dr. Pourhassan still owned some 3,234,575 out of 517,980,693 shares of Common Stock of CytoDyn (0.62%). *See United States v. White*, 620 F.3d 401, 416 (4th Cir. 2010) (Court took judicial notice of dataset, which is simply a compilation of information available in the public record), citing *Hall v. Virginia*, 385 F.3d 421, 424 n.3 (4th Cir.2004) (taking judicial notice of public records); *see also United States v. Briddle*, 212 F. Supp. 584, 589 (S.D. Cal. 1962) (District Courts have “ the power to receive evidence— including evidence adduced by means of judicial notice— upon the hearing of the defendants’ motions to dismiss the indictment at bar”); *United States v. Gordon*, 634 F.2d 639, 642 (1st Cir. 1980) (“The district judge was free to dispose of the motion [to dismiss the indictment] . . . by taking judicial notice of the proceedings which gave rise to the defense of double jeopardy.”); and *United States v. Pitt-Des Moines, Inc.*, 970 F. Supp. 1346, 1349 (N.D. Ill. 1997) (on a motion to dismiss an indictment “the court may take judicial notice of matters of public record”).

² As footnote 1 above reveals, this is not surprising because Dr. Pourhassan provided a substantial amount of these sale proceeds to CytoDyn itself so that CytoDyn could continue its important work.

2. Dr. Pourhassan’s alleged misrepresentation regarding the submission to the FDA of a “complete” BLA (Indictment ¶ 39).

Likewise, there is a fatal flaw – and further lack of notice – with respect to a lynchpin allegation that Dr. Pourhassan “misrepresented in a press release that a ‘complete’ BLA had been submitted to the FDA on April 27, 2020.” Indictment ¶ 16. In fact, the Indictment lacks any non-conclusory allegation that Dr. Pourhassan *knew* that his co-defendant, Kazem Kazempour, submitted an incomplete BLA to the FDA. In a criminal prosecution for securities fraud, there must also be a showing “that the defendant acted ‘willfully,’ that is, with a realization that [he] was acting wrongfully.” *United States v. Stewart*, 305 F. Supp. 2d 368, 371 (S.D.N.Y. 2004) (citing *United States v. Dixon*, 536 F.2d 1388, 1395 (2d Cir. 1976)). Instead, the Indictment dances around this absent allegation, with claims that: (a) Dr. Pourhassan directed defendant Kazempour to submit a “short” BLA – and relies on an illogical leap that “short” somehow must mean “incomplete” (*see* Indictment ¶ 16); and (b) defendant Kazempour directed Executive 1 to inform Dr. Pourhassan that the BLA was incomplete – with *no allegation* that Executive 1 did so (*see* Indictment ¶¶ 17,18). Even more, the Indictment acknowledges that when the BLA was submitted to the FDA, the cover letter to the BLA accurately disclosed that the BLA was incomplete. Indictment, at 38.

Finally, the Indictment points to three corrective press releases issued by CytoDyn on May 8, 2020, May 13, 2020 and June 8, 2020, “further clarif[ying] the status of [its] submission of its [BLA]”, informing the public that CytoDyn had indeed submitted the remaining parts of the BLA, and referring to the FDA’s acknowledgement letter of the BLA filing. Indictment ¶¶ 46-48. These corrective press releases further demonstrate the lack of notice. Indeed, had Dr. Pourhassan been on notice that his alleged conduct was a purported crime, he would not have publicly acknowledged that “crime” once, let alone three times in three separate press releases.

3. Dr. Pourhassan’s alleged misrepresentations regarding the timeliness for submission of the BLA (Indictment ¶¶ 28 - 35).

The Indictment’s allegations regarding Dr. Pourhassan’s expectations with respect to the timing of the BLA submission also do not demonstrate that Dr. Pourhassan was on notice that his conduct amounted to a crime. For example, the Indictment alleges that on or about April 9, 2020, CytoDyn submitted its quarterly SEC filing on SEC Form 10-Q stating that “We expect to submit the remaining two sections of the BLA in the [sic] April of 2020.” Indictment ¶ 35. The Indictment then claims that this statement was “materially false and misleading” because Dr. Pourhassan “knew that data and information required by the FDA was not available to submit by the end of April 2020 and, therefore, the remaining two sections of the BLA could not be submitted on that timeline.” As *Employees’ Retirement System of Baton Rouge & Parish of East Baton Rouge* states however, such “positive” opinions of expectation are simply not against the law. Moreover, such statements of positive and optimistic corporate “expectation” are not actionable, and amount to mere puffery. 61 F.4th at 386; *In re Rigel Pharms., Inc. Sec. Litig.*, 697 F.3d 869, 880 (9th Cir. 2012); *Shah v. GenVec, Inc.*, No. CIV.A. DKC 12-0341, 2013 WL 5348133, at *14 (D. Md. Sept. 20, 2013) (noting that “soft expressions of optimism” are not actionable).

4. Allegations that Dr. Pourhassan Used CytoDyn’s August 14, 2020 10-K filing to mislead investors about the prospects for and timing of resubmitting a completed BLA to the FDA (Indictment ¶ 50).

With respect to these allegations, for example, the Indictment is simply misleading, and cannot have put Dr. Pourhassan on notice that his conduct could amount to a crime. The Indictment claims that CytoDyn’s 10-K filing “concealed the true nature of the FDA’s numerous concerns with the BLA submission . . . and . . . suggested that the FDA merely wanted more information about leronlimab.” Indictment at 23.

Yet this very 10-K filing which is incorporated into the Indictment and its content cannot be disputed, and is otherwise subject to judicial notice as explained above, contradicts the Indictment’s allegations. Indeed, CytoDyn’s August 2020 10-K filing specifically disclosed that the “FDA informed the Company its BLA did not contain certain information needed to complete a substantive review and therefore, the FDA would not file the BLA,” noting that CytoDyn received a “Refusal to File” letter from the FDA regarding its BLA filing in July 2020. *See* Form 10-K, CytoDyn Inc. (August 14, 2020).³

In similar circumstances, courts in the Fourth Circuit and other circuits have repeatedly found that a defendant did not make a material, false statement, and certainly did not do so with intent. *See Janies v. Cempra, Inc.*, 816 F. App’x 747, 751 (4th Cir. 2020) (Court found that public disclosures undermine the contention “that the defendants acted with the intent to deceive, or that their alleged misstatements represent ‘such an extreme departure from the standard of ordinary care’ that the danger of misleading the plaintiff ‘was either known . . . or so obvious that the defendant[s] must have been aware of it’”) (citations omitted); *see also Tongue v. Sanofi*, 816 F.3d 199, 212 (2d Cir. 2016) (Court examined statements regarding expected timing and likelihood of FDA approval in Defendants’ offering documents and concluded there is no “serious conflict between the FDA’s interim, albeit repeated, concerns about methodology and Defendants’

³ This is a document referenced in the Indictment (*see* ¶ 50) and its content cannot be disputed; therefore the Court may consider this public SEC filing here. *See United States v. Covington*, 395 U.S. 57, 60 (1969); *United States v. Levin*, 973 F.2d 463, 469 (6th Cir. 1992) (“[T]he district court correctly concluded from *undisputed extrinsic evidence* . . . [that the] government was, as a matter of law, incapable of proving beyond a reasonable doubt the requisite intent required to convict the appellees”) (emphasis in original); *see also United States v. Cooper*, 77 F.3d 471 (Table), 1996 WL 67171 (4th Cir. 1996).

optimism about FDA approval” (citing *Omnicare, Inc. v. Laborers Dist. Council Constr. Indus. Pension Fund*, 575 U.S. 175, 188 (2015))).

5. Allegations that the FDA had a different opinion from that of Dr. Pourhassan and CytoDyn regarding the significance of certain data related to CytoDyn’s COVID-19 trials (Indictment at 30-33).

The Indictment’s allegations surrounding Dr. Pourhassan’s statements involving CytoDyn’s COVID-19 clinical trials also do not demonstrate that Dr. Pourhassan had sufficient notice that issuing these statements amounted to a crime. The Government claims that Cytodyn omitted certain material information from its various press releases, which allegedly included “data [which] not been run through the proper statistical tests to correct for multiplicity and therefore were not statistically significant,” as determined by the FDA (Indictment at 30-31).

Again, the law in the Fourth Circuit and other circuits demonstrate that the Government failed to move its allegation from a mere disagreement to actionable misrepresentation or omission. *See Lerner v. Nw. Biotherapeutics*, 273 F. Supp. 3d 573, 589 (D. Md. 2017) (“The fact that ‘the FDA does not consider a p-value of 0.05 to be the de facto measure of statistical significance,’ . . . does not render Defendants’ representations false or misleading.”); *see also DeMarco v. DepoTech Corp.*, 149 F. Supp. 2d 1212, 1225 (S.D. Cal. 2001) (“Although Plaintiffs may have established a legitimate difference in opinion as to the proper statistical analysis, they have hardly stated a securities fraud claim.”); *In re Adolor Corp. Sec. Litig.*, 616 F. Supp. 2d 551, 568 n.15 (E.D. Pa. 2009) (finding no “false or misleading” statement where plaintiffs’ statistician identified what he believed were problems with a defendant’s statistical analysis of a clinical trial, and plaintiffs merely alleged a disagreement about “how to conduct and analyze a study”). Indeed, the Indictment’s allegations regarding Dr. Pourhassan’s statements in a video posted on September 22, 2021 (Indictment at 33) stand as further proof that he did not have fair notice that statements to the public reflecting an optimistic view of CytoDyn’s COVID clinical trials could constitute a

crime under the federal securities law. Dr. Pourhassan's statements therein, as alleged in the Indictment, are nothing more than expressions of optimism: "textbook examples of puffing statements that reasonable investors cannot rely upon." *Emps.' Ret. Sys. of Baton Rouge & Par. of E. Baton Rouge*, 61 F.4th at 386.

Accordingly, and consistent with the above examples, the Indictment's allegations do not otherwise demonstrate that Dr. Pourhassan had notice that his conduct was criminal.

D. The Indictment Does Not Sufficiently Allege a Criminal Offense

In the alternative, the above discussion also demonstrates that the Indictment fails to state the elements of the offenses as a matter of law, and therefore dismissal is also appropriate under Federal Rule of Criminal Procedure 12(b)(3)(B)(5). To properly allege securities and wire fraud, the Indictment must allege that Dr. Pourhassan made a false statement of material fact, and that he did so knowingly and willfully. *See Stewart*, 305 F. Supp. 2d at 371 ("In a criminal prosecution [for securities fraud], the Government must also prove that the defendant acted 'willfully,' that is, with a realization that [he] was acting wrongfully." (citing *Dixon*, 536 F.2d at 1395)); *see also United States v. Wynn*, 684 F.3d 473, 478 (4th Cir. 2012) ("[T]he mail fraud and wire fraud statutes have as an element the specific intent to deprive one of something of value through a misrepresentation or other similar dishonest method, which indeed would cause him harm."). Counts Eleven through Thirteen, the insider trading charges, are derivative of these allegations. Indictment at 38-39.

The Fourth Circuit has instructed that "[a]n indictment must contain the elements of the offense charged, fairly inform a defendant of the charge, and enable the defendant to plead double jeopardy as a defense in a future prosecution for the same offense." *United States v. Loayza*, 107 F.3d 257, 260 (4th Cir. 1997) (citing *United States v. Daniels*, 973 F.2d 272, 274 (4th Cir. 1992)).

In reviewing a motion to dismiss an indictment for failure to state an offense, a district court examines only the legal sufficiency of the indictment's allegations. *See United States v. Oaks*, 302 F. Supp. 3d 716, 720 (D. Md. 2018) (citing *United States v. Terry*, 257 F.3d 366, 371 (4th Cir. 2001) (King, J., concurring)).

The discussion above, especially the Fourth Circuit's rejection of the Indictment's theory of fraud and Section II.C., demonstrates that the Indictment fails to allege that Dr. Pourhassan engaged in a crime, including the failure to allege that he knowingly made false and material statements. Indeed, as that section explains, each of the alleged false statements that the Indictment attributes to Dr. Pourhassan either fail to allege that Dr. Pourhassan acted knowingly (e.g. statements about an allegedly incomplete BLA), or such statements are simply not actionable (e.g. statements of positive expectation, opinion, different opinion than FDA or otherwise true). Thus, the Indictment must be dismissed for this reason as well.

CONCLUSION

For all these reasons, Dr. Pourhassan asks this Court to dismiss the Indictment against him.

Dated: Washington D.C.
July 25, 2023

Respectfully submitted,

Linklaters LLP

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CERTIFICATE OF SERVICE

I hereby certify that on July 25, 2023, a copy of the foregoing was filed via CM/ECF, which automatically sends notice of such filing to all parties in this matter, including:

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**UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MARYLAND**

UNITED STATES OF AMERICA,

Plaintiff,

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NADER POURHASSAN, and
KAZEM KAZEMPOUR,

Defendants.

Case No. 8:22-cr-00440-PX

[PROPOSED] ORDER

Upon consideration of Defendant Nader Pourhassan's Motion to Dismiss the Indictment, and all papers submitted in support and in opposition, it is this ____ day of _____, 2023, hereby:

ORDERED that the Motion is **GRANTED**; and it is further

ORDERED that Counts One, Two, Four, Five, Six, Nine, Ten, Eleven, Twelve and Thirteen of the Indictment are dismissed with prejudice.

Hon. Paula Xinis
United States District Judge